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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,175	05/16/2007	Stefan Golz	Le A 36 839	7833
35969	7590	05/22/2009	EXAMINER	
Barbara A. Shimei Director, Patents & Licensing Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor Tarrytown, NY 10591			CARLSON, KAREN C	
			ART UNIT	PAPER NUMBER
			1656	
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			05/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,175	Applicant(s) GOLZ ET AL.	
	Examiner Karen Cochran Carlson	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,11-13 and 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9,14,15,20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/16/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of Group 1, Claims 1, 4-7, 9, 14, and 21, in the reply filed on March 16, 2009 is acknowledged. The traversal is on the ground(s) that it would not be an undue search burden to examine Groups 1, 4, 5, and 9 drawn to a nucleic acid having SEQ ID NO: 1 and encoding SEQ ID NO: 2. Upon search and reconsideration, the Examiner has rejoined Groups 1, 4, 5, and 9 and will examine Claims 1, 4-9, 14, 15, 20, and 21.

Applicants also urge that the groups were searched by the International Searching Authority and should be examined herein. This is not found persuasive because these searches are not overlapping. Upon allowance of claims, the groups can be revisited and rejoinder may occur based on the allowable claims.

The requirement is still deemed proper and is therefore made FINAL.

Claim 10 has been canceled. Claims 1-9 and 11-21 are currently pending. The Examiner has withdrawn Claims 2, 3, 11-13, and 16-19 from further consideration because these claims are drawn to non-elected inventions. Claims 1, 4-9, 14, 15, 20, and 21 are currently under examination.

Benefit of priority is set to September 16, 2003.

Claims 14, 15, 20, and 21 provide for the use of nucleic acid or protein, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

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merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14, 15, 20, and 21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-9, 14, 15, 20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, stringent conditions are not set forth in the claims or defined in the specification. Therefore, this term cannot be understood by the skilled artisan.

In Claim 1, it is not understood what is intended by the limitation that the nucleic acid differs from a nucleic acid that hybridizes to SEQ ID NO: 1 by the degeneracy of the genetic code, that is, this claim limitation appears to be a reach through limitation because one cannot know what the degenerate code of an unknown nucleic may be.

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In Claim 1, the term "homology" is used. This term is a qualitative term and not a quantitative term; therefore, one skilled in the art cannot know what 95% or 65% homology means.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-9, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Inouye et al. (1993; Cloning and sequence analysis of cDNA for the Ca²⁺-activated photoprotein, clytin. FEBS 315(3): 343-346).

Inouye et al. teach nucleic acid encoding clytin, this nucleic acid sharing 50.9% identity with SEQ ID NO: 1 and encoding clytin sharing 77.5% identity with SEQ ID NO: 2. The nucleic acid comprises at least 10 consecutive nucleotides from SEQ ID NO: 1, for example, nucleotides 105-147 of the nucleic acid taught in Inouye et al. are the same as nucleotides 221-263 of instant SEQ ID NO: 1. The nucleic acid encoding clytin was placed into vector pBluescript (page 344. left col, last line), the vector was transformed into E. coli (page 344. left col, last line), and expressed and purified therefrom (page 344, right col., line 9).

Therefore, Inouye et al. teach a nucleic acid whose complementary strand would be expected to hybridize with SEQ ID NO: 1 and encoding a photoprotein because the

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nucleic acids share high sequence identity and clytin is a photoprotein (**Claim 1c, d**).

Claim 1e and 1f are included in this rejection because one cannot know which parts are considered to be homologous, such that they are 95% or 65% homologous to SEQ ID NO: 1 – see the rejection under 112/2 above. The nucleic acid encoding clytin is an oligonucleotide comprising at least 10 consecutive nucleotides of SEQ ID NO: 1 (**Claim 7**). Inouye et al. teach placing the nucleic acid into a vector (**Claim 5**) and therefore having a 5' functional promoter (**Claim 4**). The vector was placed into E. coli, an organism (**Claim 6**), and the polypeptide was expressed therefrom (**Claim 9**); therefore, the nucleic acid was used as a marker or reporter gene (**Claim 14**) and the protein a label or reporter (**Claim 15**). Clytin is the protein encoding by the nucleic acid taught in Inouye et al. (**Claim 8**).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson whose telephone number is 571-272-0946. The examiner can normally be reached on 6:00 AM - 4:00 PM, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656